

### **REMARKS**

This responds to the Office Action dated April 1, 2009.

Claim 1 is amended, claim 82 is canceled; as a result, claims 1-10, 12-14, 73-79, 81, and 83-84 are now pending in this application.

#### **§ 103 Rejection of the Claims**

Claims 1-10, 12-14, 73-79, and 81-84 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dennis et al. (U.S. Patent No. 6,114,164, hereinafter “Dennis”) in view of Kofidis et al. (Journal of Thoracic and Cardio. Surg., hereinafter “Kofidis”), Farb et al. (U.S. Patent No. 6,048,722, hereinafter “Farb”), Bursac et al. (Am. J. Physiol. 277, hereinafter “Bursac”) and Terracio et al. (In Vitro Cell. And Develop Bio., hereinafter “Terracio”).

#### ***Claim 1***

Claim 1 is amended to better describe the claimed subject matter.

Applicant respectfully traverses the rejection and submits that for at least reasons discussed below, the Office Action does not set forth a proper *prima facie* case of obviousness.

#### **A) The Rejection is Based on Reasoning with Improper Application of Case Law.**

Applicant respectfully submits that the cited portions of Dennis, Kofidis, Farb, Bursac, and Terracio, individually or in combination with each other and reasoning given in the Office Action, do not provide the claimed subject matter. For example, Applicant is unable to find in the cited portions of Dennis, Kofidis, Farb, Bursac, and Terracio, individually or in combination, among other things, one or more biological stimulus agents selected from protein and nucleic acid, and a biological treatment administration module including the one or more biological stimulus agents, as recited in claim 1. For at least the following reasons, the Office Action does not provide a proper reason that addresses this deficiency of the cited references.

The Office Action asserts, in paragraph 5, on page 6:

Note positive recitation in the claims that the apparatus includes a protein or nucleic acid agent does not further patentably distinguish the structure of the claim because “Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). See MPEP 2115.

However, the line of cases cited in MPEP § 2115, including *Ex parte Thibault*, “is limited to claims directed to machinery which works upon an article or material in its intended use.”

MPEP § 2115. The biological treatment administration module as recited in claim 1 does not “work upon” the one or more biological stimulus agents selected from protein and nucleic acid as recited in claim 1<sup>1</sup>. Therefore, it is believed that *Ex parte Thibault* and MPEP § 2115 do not apply.

The Office Action further asserts, in Response to Arguments (paragraph 6), on page 9:

... it is fundamental that an apparatus claim defines the structure of the invention and not how the structure is used in a process, or what materials the structure houses in carrying out the process. *Ex parte* (sic) *Masham*, 2 USPQ2d 1647, 1648 (BPAI 1987). See also *In re Yanush*, 477 F.2d 958, 959, 177 USPQ 705, 706 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 1032, 168 USPQ 530, 534 (CCPA 1971); *In re Casey*, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967).

*Ex parte Masham* holds that “the recitation of ‘completely submerged in the developer material’ does not impose any structural limitations upon the claimed apparatus”. See also MPEP § 2115. *In re Yanush*, *In re Finsterwalder*, and *In re Casey* are also related to recitation of intended use of a claimed structure<sup>2</sup>. Thus, *Ex parte Masham*, *In re Yanush*, *In re Finsterwalder*, and *In re Casey* are all related to how a claimed structure is intended to be used. In contrast, the one or more biological stimulus agents recited in claim 1 are part of the claimed apparatus, rather than the intended use of the claimed apparatus<sup>3</sup>.

Additionally, it is unclear how any of *Ex parte Masham*, *In re Yanush*, *In re Finsterwalder*, and *In re Casey* would support the assertion that “it is fundamental that an apparatus claim defines the structure of the invention and not ... what materials the structure

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<sup>1</sup> The claimed apparatus “works upon” the cells recited in claim 1. Thus, the cells constitute the “article or material” mentioned in MPEP 2115, while the one or more biological stimulus agents are part of the claimed apparatus, as recognized in the Office Action (paragraph 6, page 9).

<sup>2</sup> *In re Yanush* holds that “[w]hether a vibrator is operated gently to settle materials in a mold or more forcefully to “hammer” them is a process limitation which does not limit or define the claimed apparatus.” *In re Finsterwalder* holds that “the fact that appellant discloses the apparatus as advantageous in the ‘free cantilever’ method of construction will not save the claims if the apparatus defined thereby would have been obvious to a person of ordinary skill in the bridge-construction art intending to use it in a somewhat different construction method.” *In re Casey* holds that “[p]resenting adhesive tape to a roll in such a way as to adhere it to the roll and causing movement of the roll ‘while adhesive tape is adhered to said surface’ are method steps and cannot properly confer patentability on an apparatus claim.”

<sup>3</sup> The intended use of the claimed apparatus is to provide *in vitro* conditioning of cells prior to a cell therapy administrated into a body having a myocardium, as recited in the preamble of claim 1, rather than housing the one or more biological stimulus agents.

houses in carrying out the process.” Applicant respectfully requests a clarification showing what in any of these cases supports the assertion, or withdrawal of the rejection.

Furthermore, even if the assertion is correct with respect to “what materials the structure houses”, the one or more biological stimulus agents as recited in claim 1 are not merely materials housed in the claimed structure. The Office Action states, under Response to Argument, in the same paragraph on page 9, that “it is fundamental that an apparatus claim defines the structure of the invention and not how the structure is used in a process, or what materials the structure houses in carrying out the process” but also that “[t]he Examiner recognizes that the biological stimulus agents have been positively recited as part of the claimed device”. It is unclear how a recitation of a structure being part of the claimed device is also a recitation of an intended use of the claimed device or a recitation of materials housed in the claimed device. Thus, the reasoning supporting the rejection is unclear.

Regardless of how it is considered in the Office Action, Applicant respectfully submits that claim 1 recites the one or more biological stimulus agents as an essential structural element, rather than an article or material being worked upon or an intended use of the claimed apparatus. Therefore, Applicant believes that none of *Ex parte Thibault*, *Ex parte Masham*, *In re Yanush*, *In re Finsterwalder*, and *In re Casey* supports the rejection.

**B) The Rejection Is Not Supported by Clearly Articulated Reasoning for the Combination of References.**

Applicant also respectfully submits that the Office Action does not provide a proper reason for the combination of Dennis, Kofidis, Farb, Bursac, and Terracio. “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007). As to the reason for combining all five cited references, the Office Action merely states, in paragraph 5, on page 6, that “[t]he additional references as discussed in the rejection of record provide the motivation for controlling the different stimulation devices for emulating the condition found in vivo.” It is unclear what the motivation is because, for example, Applicant is unable to find in the cited references and the Office Action a reason for expecting an apparatus

combining all of the five cited references as set forth in the Office Action to produce an additional benefit relative to a subset thereof. Therefore, Applicant respectfully traverses the assertion of obviousness as a conclusory statement without support of proper reasoning, and submits that the Office Action does not provide clearly articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

**C) The Rejection Is Not Supported by A Reasonable Expectation of Success in the Combination of the References.**

The Office Action cites *KSR* to state that “the rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art.” However, Applicant is unable to find in the Office Action why “the combination yielded nothing more than predictable results to one of ordinary skill in the art”.

For example, the Office Action asserts that Kofidis and Farb disclose the introduction of chemical stimuli to cells. However, the chemical stimuli in Kofidis (calcium and epinephrine) are neither protein nor nucleic acid, and are added to strips having cardiomyocytes to increase the force of contraction, and the chemical stimuli in Farb are added to discern their effect on membrane physiology of a cell *in vitro* after cytoplasmic delivery. In contrast, the biological stimuli in the apparatus of the invention are selected from protein and nucleic acid that in an effective amount enhance one or more of engraftment, survival, and differentiation of cells after their administration into the body.

Applicant respectfully requests reconsideration and allowance of claim 1.

*Claims 2-10, 12-14, 73-79, and 81-84*

Claim 82 has been cancelled.

Applicant respectfully traverses the rejection. Claims 2-10, 12-14, 73-79, 81, and 83-84 are dependent on claim 1, which is believed to be patentable for at least the reasons set forth

above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 2-10, 12-14, 73-79, 81, and 83-84.

Applicant respectfully requests reconsideration and allowance of claims 2-10, 12-14, 73-79, 81, and 83-84.

### **CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6965 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 3rd day of August, 2009.

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Name

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